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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/607,247	06/25/2003	Jeffrey A. Hubbell	UTSB 493 CIP CON (5)	4957

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EXAMINER	
NAFF, DAVID M	

ART UNIT	PAPER NUMBER
1651	

DATE MAILED: 01/31/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/607,247	HUBBELL ET AL.	
	Examiner	Art Unit	
	David M. Naff	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 November 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *32 and 36-42* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *32 and 36-42* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *25 June 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *6/25/03*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

A response of 11/2/05 to a restriction requirement of 8/2/05 amended claim 32, added new claims 36-42, canceled claims 1-31 and 33-35, and elected Group II claim 32 without traverse.

Since claims 36-42 are dependent on claim 32, these claims are included with 32 in Group II.

Claims examined on the merits are 32 and 36-42, which are all claims in the application.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 32 and 36-42 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are confusing by "textured material" in the last line of claim 32 being indefinite as to meaning and scope. Being "textured" is relative and subjective. It would be uncertain as to characteristics of materials that make them textured as compared to characteristics that result in the materials not being textured.

Claim 41 is unclear as to components that form the mixture in line 3 and the mixture in line 4, and the difference in the mixture in

line 3 from the mixture in line 4. Applying to a surface as in line 3 would not appear to form a mixture as in line 4.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., In re Berg, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); In re Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); In re Van Ornum, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In re Thorington, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement. Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 32 and 36-42 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-22 of U.S. Patent No. 5,843,743 or claims 1-20 of U.S. Patent No. 5,834,274. Although the conflicting claims are not identical, they are not patentably distinct from each other because the presently claimed substrate having a polymeric coating formed by free radical polymerization of a macromer would have been obvious from the substrate having a polymeric coating claimed by the '743 patent or the tissue having a polymeric coating claimed by the '274 patent where

the polymeric coating is formed by radical polymerization of a macromer. The substrate of the '743 patent can be textured (claim 19), and the tissue of the '274 patent is a textured material.

Double Patenting

Claims 32 and 36-42 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-4 of U.S. Patent No. 6,632,446 B1 in view of Hsu (5,047,020).

The present claims require a substrate having a polymeric coating formed by free radical polymerization of a macromer, wherein the coating contains one or more polysaccharides and the substrate is textured.

The claims of the patent require coating a substrate by mixing a macromer with a polymerization initiator, applying the mixture to a substrate and causing polymerization of the macromer.

Hsu discloses a substrate surface having an anti-thrombogenic coating containing heparin (col 4, lines 25-33). The substrate can be a resin substrate for contact with blood (col 7, lines 10-25) that can be cellular, non-cellular, porous or non-porous (col 7, lines 27-30).

It would have been obvious to include heparin, which is a polysaccharide, in the coating of the patent claims as suggested by Hsu to make the coating anti-thrombogenic.

Double Patenting

Claims 32 and 36-42 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-

16 of U.S. Patent No. 5,573,934 or claims 1-69 of U.S. Patent No. 5,529,914 in view of Hsu.

The present claims are described above.

The claims of the '934 patent require encapsulating or coating a biological material and the claims of the '914 patent require encapsulating a biological material by combining a biological material with a macromer and polymerizing the macromer.

Hsu is described above.

It would have been obvious to substitute for the biological material of the patent claims, the substrate taught by Hsu to provide a substrate for contact with blood. A cellular or porous substrate disclosed by Hsu is a textured material.

Double Patenting

Claims 32 and 36-42 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-17 of U.S. Patent No. 6,465,001 in view of Hsu.

The present claims and Hsu are described above.

The patent claims require treatment of a medical condition at a site by applying a polymerization initiator and a macromer, and polymerizing the macromer to form a cross-linked polymeric material. The polymeric material can be formed on the surface of an implanted material (claim 14).

It would have been obvious to include heparin in the polymeric material of the claims of the patent as suggested by Hsu to make the polymeric material anti-thrombogenic. It would have been further

obvious to use as the implanted material of the patent claims a resin substrate as taught by Hsu to provide an article for contact with blood. The resin substrate will be a textured material.

Conclusion

The claims are free of the prior art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David M. Naff whose telephone number is 571-272-0920. The examiner can normally be reached on Monday-Friday 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

David M. Naff
Primary Examiner
Art Unit 1651

DMN
1/23/06